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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,335

09/02/2004

Eiko Kato

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

GULLEDGE, BRIAN M

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

06/08/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,335	<b>Applicant(s)</b> KATO ET AL.	
	<b>Examiner</b> Brian Gulledge	<b>Art Unit</b> 1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15, 18, 19, 21 and 26-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 18, 19, 21 and 26-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 March 2010 has been entered.

### ***Previous Rejections***

Applicants' arguments, filed 19 March 2010 and 17 May 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 15, 18-19, 21, and 26 stand rejected and claims 27-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. (*Free Rad. & Med.*, 1997, 22(5), pages 761-769) in view of Takata et al. (*J. Pharm. Sci.*, 1995, 84(1), pages 96-100) and Yasuaki (JP 62-106005).** Applicant argues that the rejection is not proper in view of the data of record that

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demonstrates that various inventive lotions unexpectedly reduce pigmentation of the skin when applied to the skin after UV exposure. The Examiner acknowledges the evidence of record, but does not consider the claims commensurate in scope with the showing (as discussed below), and as such the rejection is maintained.

**Claims 15, 18-19, 21, and 26 stand rejected and claims 27-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke et al. (*Nutrition and Cancer*, 2000, 38(1), pages 87-97) in view of Takata et al. (*J. Pharm. Sci.*, 1995, 84(1), pages 96-100).** Applicant argues that the rejection is not proper in view of the data of record that demonstrates that various inventive lotions unexpectedly reduce pigmentation of the skin when applied to the skin after UV exposure. The Examiner acknowledges the evidence of record, but does not consider the claims commensurate in scope with the showing (as discussed below), and as such the rejection is maintained.

#### ***Evidence of Unexpected Results***

The declaration filed under 37 CFR 1.132 filed 17 May 2010 is acknowledged. However, the evidence presented by this declaration, and the previously presented evidence submitted 6 October 2009 and in the instant specification is found insufficient to overcome the above rejections of claims 15, 18-19, 21, and 26-39.

The data describe tests which involved the exposure of mice to UV-radiation, and then subsequent to said exposure, and only after said exposure, the application of formulations according to the invention. The result was a decrease in the pigmentation of the mice after 28

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days. The data demonstrate that tocopherol itself has little to no effect under the conditions employed, whereas the particular tocopherol dimethylglycine ester hydrochlorides according to the invention reduced pigmentation. This difference would not be expected when the tocopherols were applied only after the single exposure to UV-radiation. However, the claims are not limited to just this scope, and do not recite a method limited to application only after a single exposure to UV-radiation.

The claims recite a method for reducing pigmentation of the skin, comprising the step of applying an effective amount of the “composition to the skin after UV exposure.” The scope of the claims encompass, for example, the conditions employed in the experiments presented in the declarations and the instant specification – UV exposure, and then after the single UV exposure application of the tocopherol-containing composition. However, the claims require no specific time frame with regards to when after UV-exposure the composition is applied, nor do the claims recite any limitations with regards to when the subject experiences multiple UV-exposures. Almost all humans, for example, have been previously exposed to UV-radiation at one point in their lives, and the use of the tocopherol-containing composition before being exposed to the next batch of UV-radiation (i.e. applying the tocopherol-containing lotion as a sunscreen before going to the beach), but after a previous exposure (such as after having gone outside once before) would thus lie within the scope of the claims as recited.

Tocopherol is known to have an effect on pigmentation: see for example figure 1 of Burke et al.<sup>1</sup> This reference discloses experiments where mice have the lotion applied before and during the experiment, and the experiment involved repeated exposures to UV-radiation

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(pages 88-89, "Materials and Methods," "Animals and Treatments"). Thus, the mice have the tocopherol applied before the initial UV-exposure, and then again after that exposure (and before the next in the series of multiple UV-exposures). The experiment shows that pigmentation is reduced when using tocopherol, and the tocopherol is applied (except for the initial application) after the subject was exposed to UV radiation. Thus, one of ordinary skill in the art would expect that by using tocopherols before being exposed (again) to UV-radiation, pigmentation could be reduced.

While the specific conditions tested and presented by the Applicant would not have been expected (tocopherols were applied to subjects that experienced only a single exposure to UV-radiation), the claims encompass within their scope methods which would have been expected to reduce pigmentation. And thus the rejections are maintained.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gullledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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<sup>1</sup> This reference is not being used substantively as part of the rejection over Weber et al., Takata et al., and Yasuaki, but rather only to demonstrate what the ordinary artisan would have expected at the time the invention was made.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612